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(54) **METHOD FOR MANIPULATING CATHETER SHAFT**

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See application file for complete search history.

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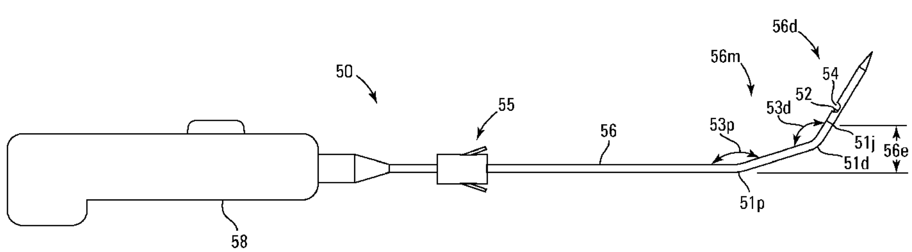
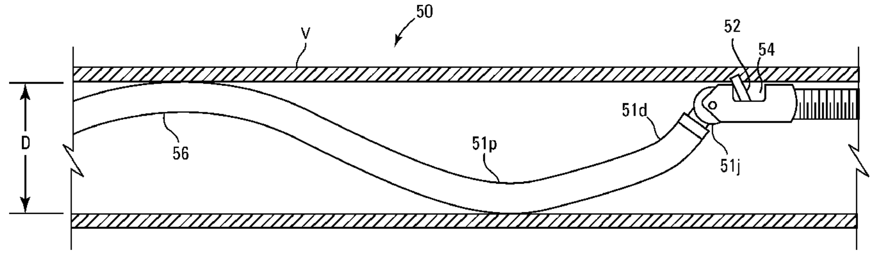
(57) **ABSTRACT**

A catheter for performing a procedure at a treatment site in the lumen of a blood vessel. The catheter includes an elongate tubular shaft having a proximal bend, a distal bend and a hinge element. A distal portion of the shaft includes a window extending through the sidewall of the shaft between the hinge element and the distal end of the elongate tubular shaft. A working element is disposed within the lumen of the elongate tubular shaft and is configured for performing the procedure through the window at the treatment site. The bends and hinge element are configured to urge the window against a wall of the vessel at the treatment site.

17 Claims, 8 Drawing Sheets





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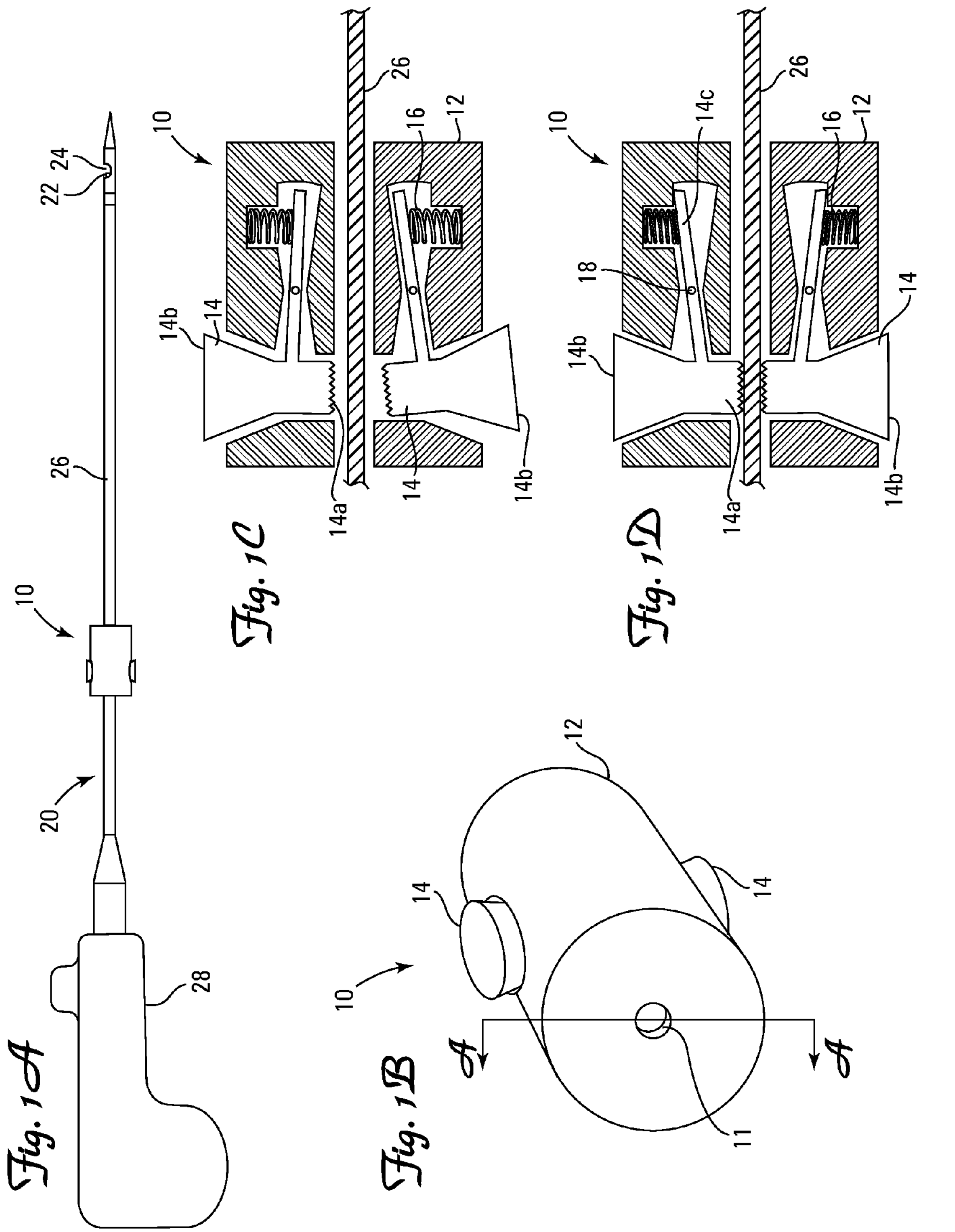

Fig. 1A

Fig. 1B

Fig. 1C

Fig. 1D

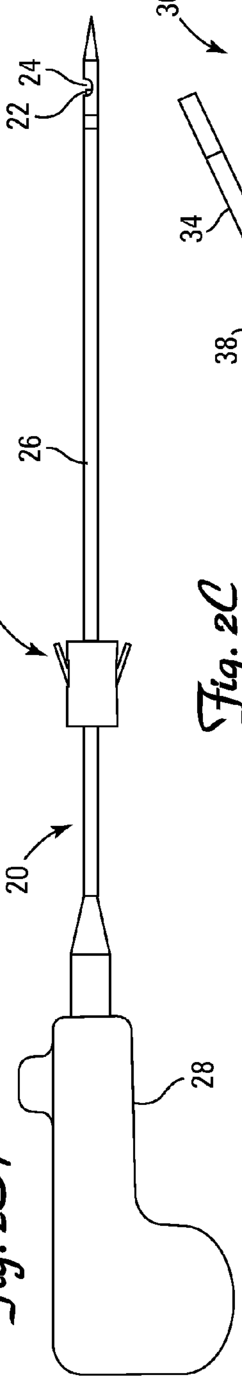

Fig. 2A

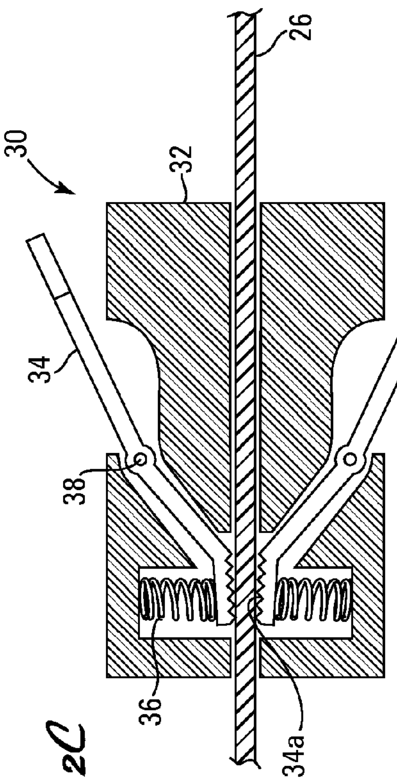

Fig. 2C

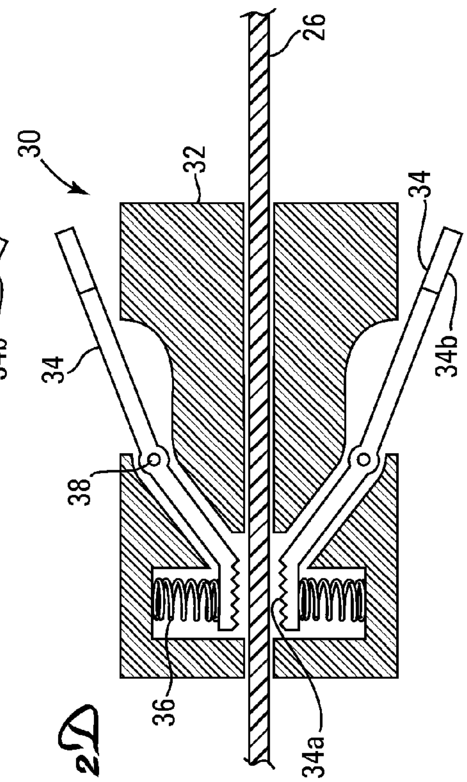

Fig. 2D

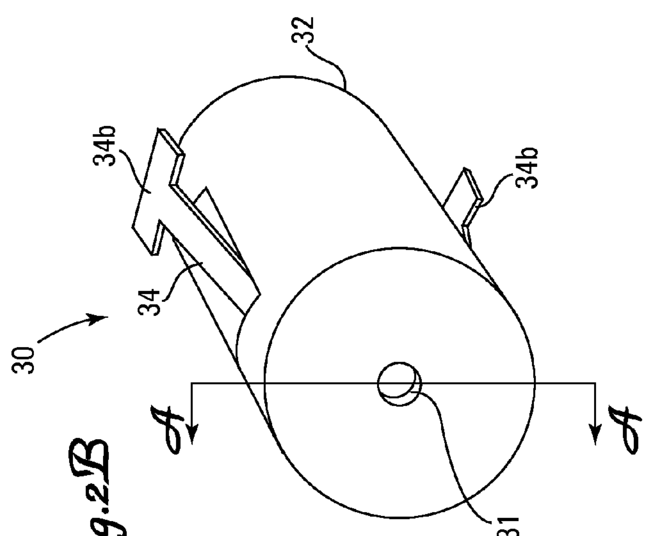

Fig. 2B

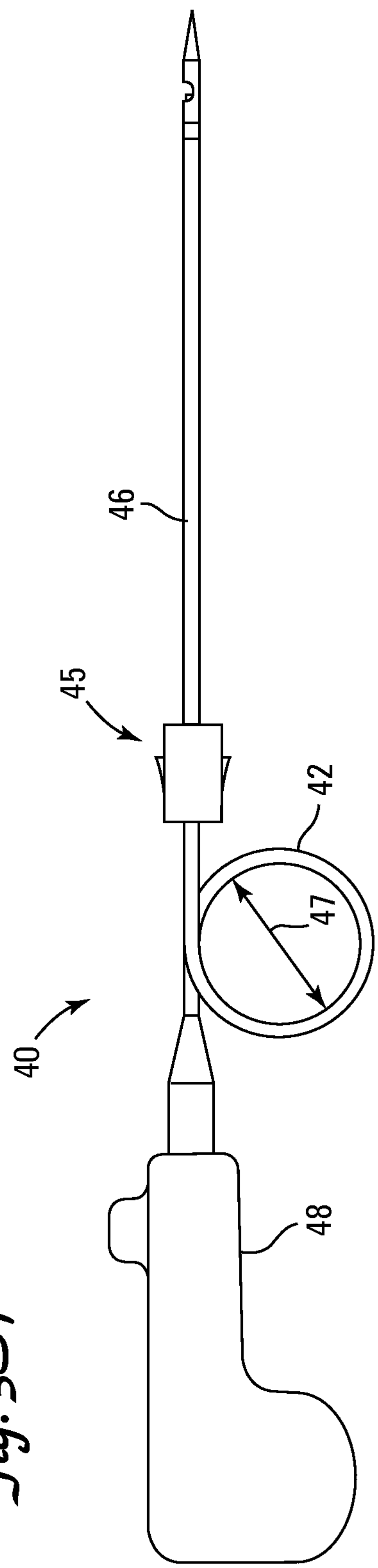

Fig. 3A

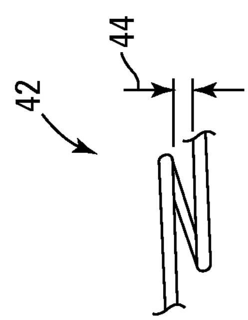

Fig. 3B

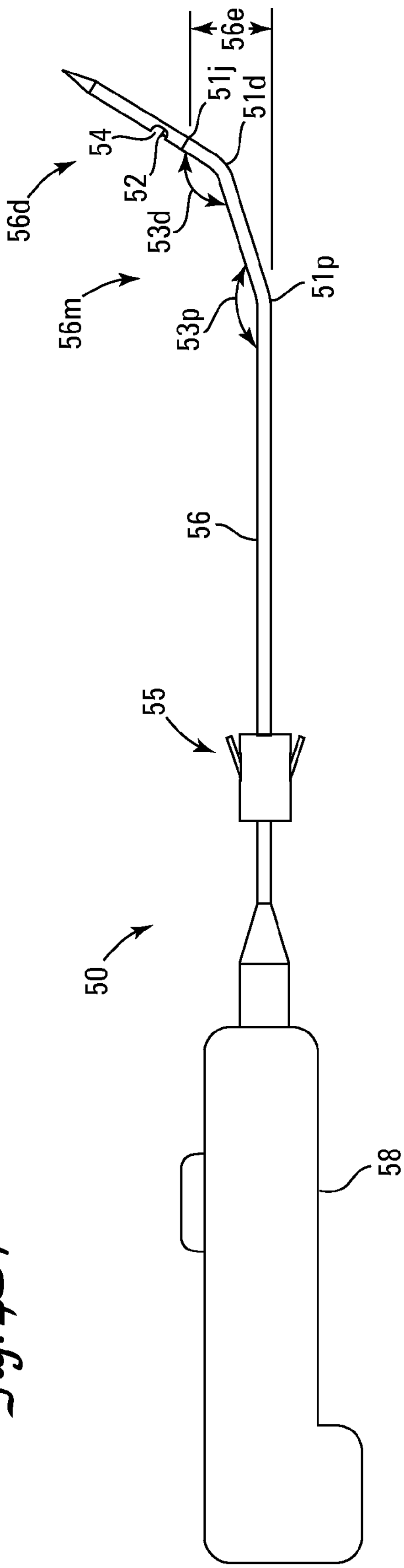

Fig. 4A

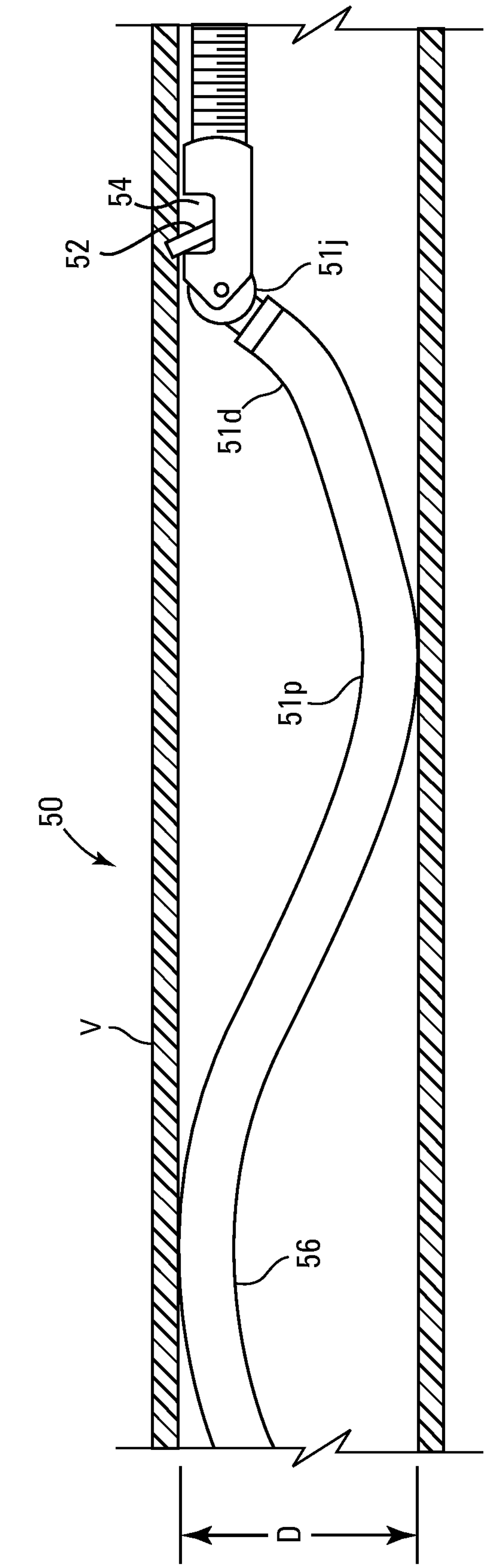

Fig. 4B

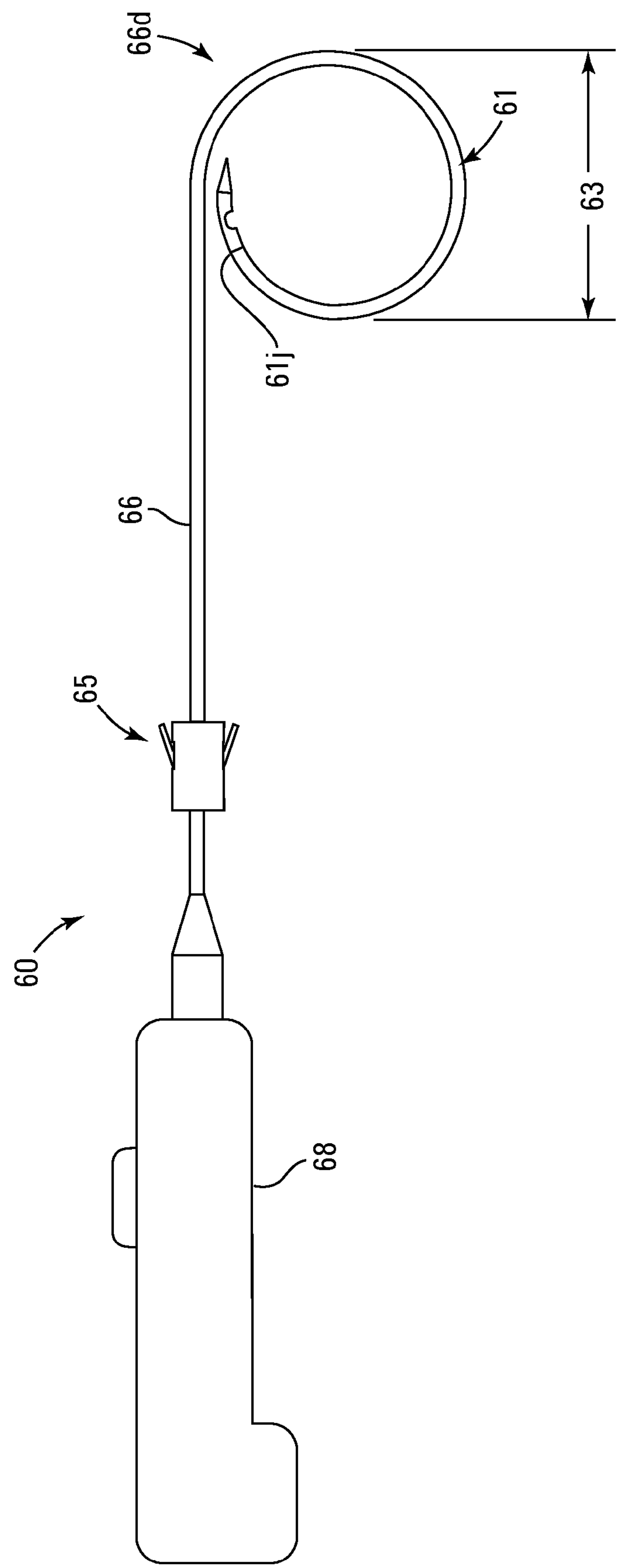

Fig. 5A

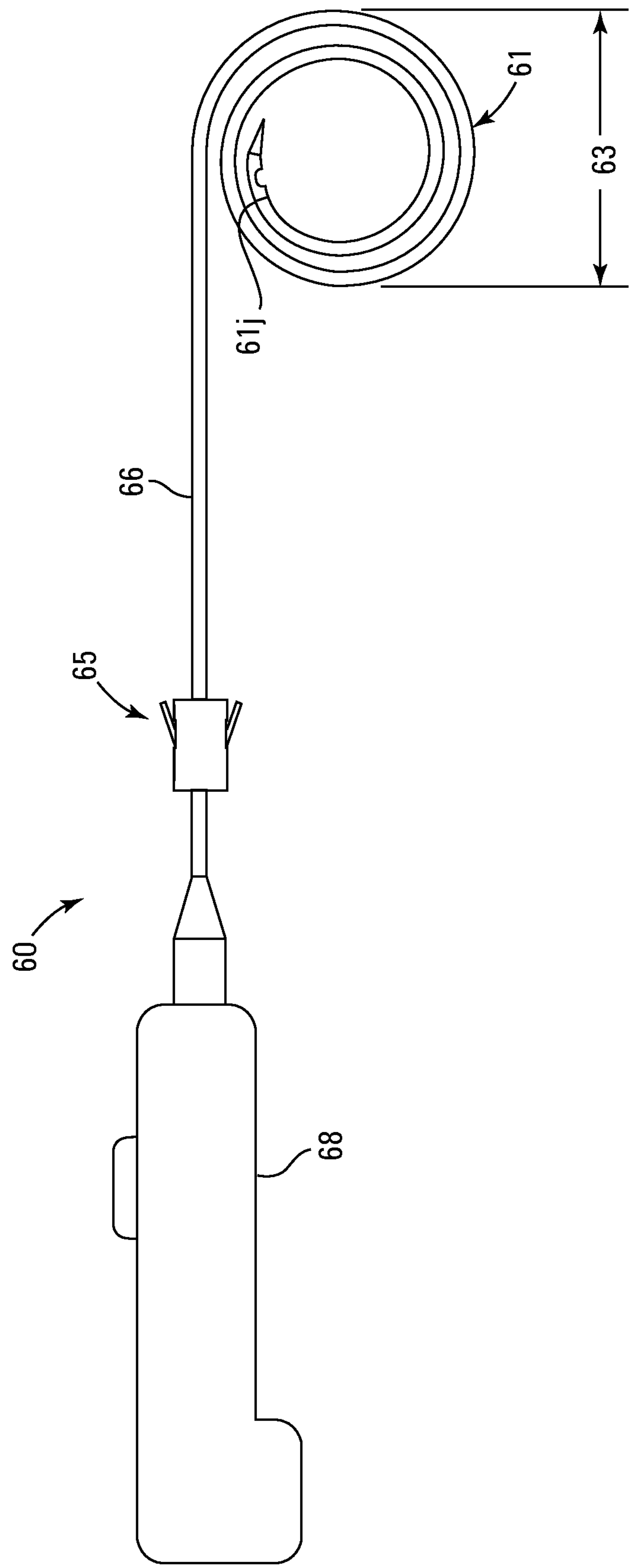

Fig. 5B

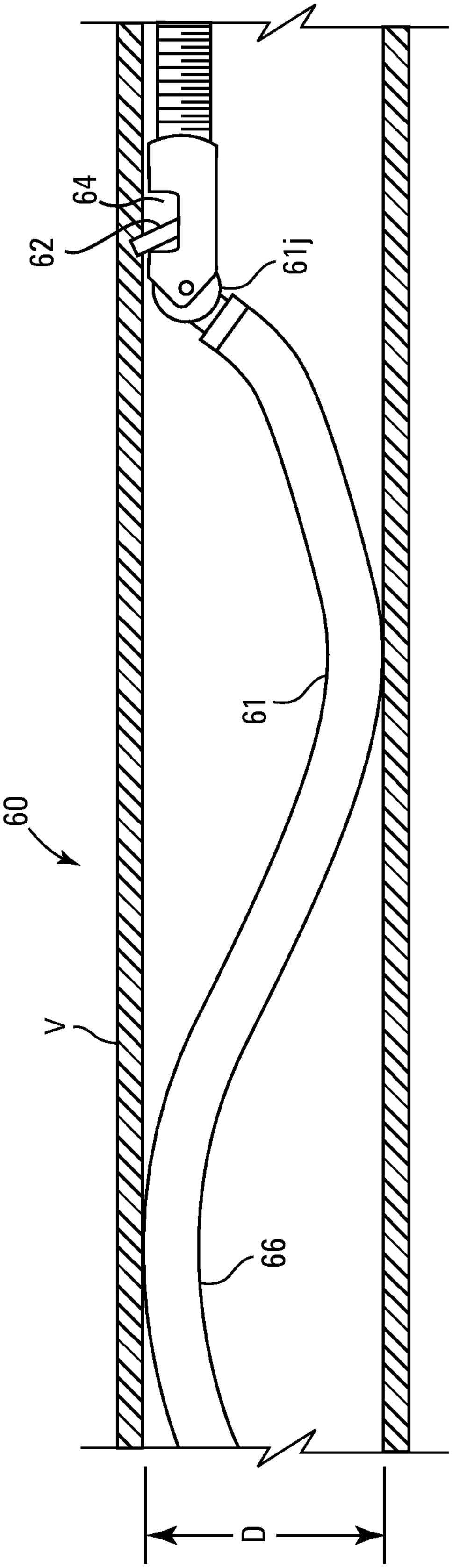

Fig. 5C

METHOD FOR MANIPULATING CATHETER SHAFT

CROSS-REFERENCE TO RELATED PATENT APPLICATIONS

The present invention claims priority to U.S. Ser. No. 12/578,204, filed Oct. 13, 2009, which claims priority to Provisional Application No. 61/122,601, filed on Dec. 15, 2008, and Provisional Application No. 61/104,836, filed on Oct. 13, 2008. The complete disclosure of each of the above-listed patent applications is hereby incorporated by reference for all purposes.

BACKGROUND

Atherectomy catheters are used to remove material from a blood vessel to open the lumen of the blood vessel and improve blood flow through the vessel.

Atherectomy catheters generally have cutters positioned at or near the distal end of the catheter. Some atherectomy catheters are designed to cut along only one portion of their distal circumference. Such 'directional atherectomy' catheters must be manipulated such that the cutter is positioned adjacent to the material to be cut. Such manipulation can involve urging the cutter against one side of a blood vessel so that material can be cut, and can involve rotating the proximal region of the catheter shaft so as cause rotation of the distal region of the catheter and thereby position the distally located directional cutter adjacent to material to be cut.

The present invention is directed to devices and methods for manipulating and urging a cutting element of an atherectomy catheter such that the cutter is positioned adjacent to the material to be cut.

SUMMARY

The present invention provides a manipulator which is used with an atherectomy catheter to rotate, translate, or both rotate and translate the catheter. The atherectomy catheter may have a cutting element that is able to extend through a window to cut material of interest. The manipulator can be actuated using one hand only.

In another aspect of the invention, an atherectomy catheter is provided with a pre-formed distal region. The pre-formed distal region urges the atherectomy catheter cutter into forcible contact with the inner wall of a vessel. When the cutting element encounters tissue, forces that tend to deflect the cutting element away from the tissue are resisted by the pre-formed distal region of the catheter.

In one aspect the invention is a catheter for performing a procedure at a treatment site in the lumen of a blood vessel, the blood vessel having a diameter D at the treatment site. The catheter comprises an elongate tubular shaft having distal and proximal ends and a sidewall defining a lumen, the elongate tubular shaft having a proximal bend, a distal bend and a hinge element, the proximal bend defining a first angle greater than zero, the distal bend defining a second angle greater than the first angle, the hinge element being spaced proximally of the distal end of the elongate tubular shaft and distally of the distal bend, the distal bend being positioned between the proximal bend and the hinge element, a distal portion of the elongate tubular shaft extending between the hinge element and the distal end of the elongate tubular shaft and a mid portion of the elongate tubular shaft extending between the hinge element and the proximal bend, the distal portion including a window extending through the sidewall between

the hinge element and the distal end of the elongate tubular shaft. The catheter further includes a working element disposed within the lumen of the elongate tubular shaft, the working element configured for performing the procedure through the window at the treatment site, the first and second angles being selected to form a maximum excursion of the elongate tubular shaft between the proximal bend and the hinge element greater than diameter D such that the window is urged against a wall of the vessel at the treatment site. The proximal and distal bends may be configured to lie within a first plane and the hinge element may configured to permit bending of the distal portion with respect to the mid portion only in the first plane. The first and second angles may selected to urge the window against the wall of the vessel at a force in the range of about 0.05 to 0.5 pounds. The first angle may be in the range of about 90° to 150° and the second angle may be in the range of about 100° to 180°. A length from the proximal bend to the distal bend may be greater that a length from the distal bend to the hinged element. A length between the proximal and distal bends may be in the range of about 0.5 to 2.0 inches and a length between the distal bend and the hinge element may be in the range of about 0.375 to 0.625 inches. The maximum excursion may be in the range of about 3 to 40 mm.

In another aspect the invention is a catheter for performing a procedure at a treatment site in the lumen of a blood vessel. The catheter includes an elongate tubular shaft having distal and proximal ends and a sidewall defining a lumen, the elongate tubular shaft having a curved distal portion with a continuously decreasing radius of curvature, the continuously decreasing radius of curvature being oriented in a first plane from a proximal end of the distal portion to the distal end of the elongate tubular shaft, the distal portion including a hinge element spaced proximally of the distal end of the elongate tubular shaft, the hinge element dividing the distal portion into a distal segment between the hinge element and the distal end of the elongate tubular shaft and a proximal segment between the hinge element and the proximal end of the distal portion, the hinge element being configured to permit the distal segment to bend with respect to the proximal segment only in the first plane, the distal segment including a window extending through the sidewall between the hinge element and the distal end of the elongate tubular shaft. The catheter further includes a working element disposed within the lumen of the elongate tubular shaft, the working element configured for performing the procedure through the window at the treatment site, the continuously decreasing radius of curvature being selected to urge the window against a wall of the vessel at the treatment site during use. The curved distal portion may form a continuous curve in the range of about 90° to 720°. A maximum curve diameter of the curved distal portion may be in the range of about 3 mm to 50 mm.

In a further aspect the invention is a method of performing a procedure at a treatment site in the lumen of a blood vessel. The method comprises providing an elongate tubular shaft having distal and proximal ends and a sidewall defining a lumen, the elongate tubular shaft having a proximal bend, a distal bend and a hinge element, the proximal bend defining a first angle greater than zero, the distal bend defining a second angle greater than the first angle, the proximal and distal bends being oriented in a first direction, the hinge element being spaced proximally of the distal end of the elongate tubular shaft and distally of the distal bend, the distal bend being positioned between the proximal bend and the hinge element, a distal portion of the elongate tubular shaft extending between the hinge element and the distal end of the elongate tubular shaft and a mid portion of the elongate tubular shaft extending between the hinge element and the proximal bend, the distal portion including a window extending through the sidewall between the hinge element and the distal end of the elongate tubular shaft. The method farther includes advancing the elongate tubular shaft through the lumen of the vessel to the treatment site; orienting the elongate tubular shaft in a position where the proximal and distal bends cause the distal portion of the elongate tubular shaft to bend with respect to the mid portion of the elongate tubular shaft at the hinge element in a second direction opposite the first direction to urge the window against a wall of the vessel in a desired location at the treatment site; and performing a procedure through the window at the treatment site with a working element disposed within the lumen of the elongate tubular shaft while the window is urged against the wall of the vessel. The hinge element may be configured to permit bending of the distal portion with respect to the mid portion only in the first and second directions.

In a further aspect the invention is a method of performing a procedure at a treatment site in the lumen of a blood vessel comprising providing an elongate tubular shaft having distal and proximal ends and a sidewall defining a lumen, the elongate tubular shaft having a curved distal portion with a continuously decreasing radius of curvature, the continuously decreasing radius of curvature being oriented in a first direction from a proximal end of the distal portion to the distal end of the elongate tubular shaft, the distal portion including a hinge element spaced proximally of the distal end of the elongate tubular shaft, the hinge element dividing the distal portion into a distal segment between the hinge element and the distal end of the elongate tubular shaft and a proximal segment between the hinge element and the proximal end of the distal portion, the hinge element being configured to permit the distal segment to bend with respect to the proximal segment only in the first direction and a second direction opposite the first direction, the distal segment including a window extending through the sidewall between the hinge element and the distal end of the elongate tubular shaft. The method further includes advancing the elongate tubular shaft through the lumen of the vessel to the treatment site; orienting the elongate tubular shaft in a position where the continuously decreasing radius of curvature of the curved distal portion causes the distal segment to bend with respect to the proximal segment at the hinge element in the second direction to urge the window against a wall of the vessel in a desired location at the treatment site; and performing a procedure through the window at the treatment site with a working element disposed within the lumen of the elongate tubular shaft while the window is urged against the wall of the vessel.

In another aspect the invention is a device for manipulating the shaft of a catheter comprising a body portion having a lumen sized to receive the shaft of the catheter, and a shaft engaging member having first and second shaft engaging surfaces enclosed within the body portion, the shaft engaging member having a locked position in which the first and second shaft engaging surfaces are configured to engage the shaft to lock the body on the shaft and an unlocked position in which the body is free to rotate and axially translate over the elongate tubular shaft. The shaft engaging surfaces may be biased in either the locked or the unlocked position.

In a further aspect the invention is a catheter for accessing a site on the wall of a blood vessel. The catheter includes an elongate tubular shaft having distal and proximal ends and a sidewall defining a lumen, the elongate tubular shaft having a first bend, a second bend spaced a predetermined distance distally of the first bend and a window extending through the sidewall, the window being positioned distally of the second bend and proximally of the distal end of the elongate tubular member, the first bend defining a first angle greater than zero, the second bend defining a second angle greater than the first angle, the first and second angles and the predetermined distance being selected to urge the window against the site on the wall of the blood vessel during use. The elongate tubular shaft may further include a hinge element spaced proximally of the window and distally of the second bend. Further, the catheter may include a working element disposed within the lumen of the elongate tubular shaft, the working element configured for performing a procedure through the window at the site on the wall of the blood vessel. The elongate tubular shaft may include a distal portion between the hinge element and the distal end of the elongate tubular shaft and the hinge element may be configured as a pivot point about which the distal portion bends. Further, the distal portion may have a longitudinal axis and the hinge element may be configured such that when the window is urged against the site on the wall of the blood vessel during nest the distal portion is positioned such that the longitudinal axis of the distal portion is substantially parallel to a longitudinal axis of the blood vessel.

In another aspect the invention is a catheter for performing a procedure at a treatment site in the lumen of a blood vessel comprising an elongate tubular shaft having distal and proximal ends and a sidewall defining a lumen, the elongate tubular shaft having a proximal bend, a distal bend and a hinge element, the proximal bend defining a first angle greater than zero, the distal bend defining a second angle greater than the first angle, the hinge element being spaced proximally of the distal end of the elongate tubular shaft and distally of the distal bend, the distal bend being positioned between the proximal bend and the hinge element, a distal portion of the elongate tubular shaft extending between the hinge element and the distal end of the elongate tubular shaft and a mid portion of the elongate tubular shaft extending between the hinge element and the proximal bend, the distal portion including a window extending through the sidewall between the hinge element and the distal end of the elongate tubular shaft, the proximal bend, distal bend and hinge element being configured to urge the window against a wall of the vessel at the treatment site. The catheter may include a working element disposed within the lumen of the elongate tubular shaft, the working element configured for performing the procedure through the window at the treatment site when the window is urged against the wall of the blood vessel during use.

These and other aspects of the invention will become apparent from the following description of the preferred embodiments, drawings and claims. The details of one or more embodiments of the invention are set forth in the accompanying drawings and the description below. Other features, objects, and advantages of the invention will be apparent from the description and drawings, and from the claims.

DESCRIPTION OF THE DRAWINGS

FIG. **1**A illustrates a schematic plan view of one embodiment of a shaft manipulator in accordance with principles of the present invention.

FIG. **1**B illustrates an isometric view of the shaft manipulator illustrated in FIG. **1**A.

FIGS. **1**C and **1**D illustrate cross sectional views along line A-A of the shaft manipulator illustrated in FIG. **1**A.

FIG. **2**A illustrates a schematic plan view of another embodiment of a shaft manipulator in accordance with principles of the present invention.

FIG. 2B illustrates an isometric view of the shaft manipulator illustrated in FIG. 2A.

FIGS. 2C and 2D illustrate cross sectional views along line A-A of the shaft manipulator illustrated in FIG. 2A.

FIGS. 3A and 3B illustrate schematic plan views of another embodiment of a shaft manipulator in accordance with principles of the present invention.

FIGS. 4A and 4B illustrate schematic plan views of yet another embodiment of a catheter in accordance with principles of the present invention.

FIGS. 5A to 5C illustrate schematic plan views of a further embodiment of a catheter in accordance with principles of the present invention.

DETAILED DESCRIPTION

Referring to the embodiment of FIGS. **1**A to **1**D, the present invention is directed to a device for manipulating a catheter shaft. The invention is described in connection with an atherectomy catheter but may be used with any other catheter.

The atherectomy catheter **20** has a working element **22** such as a cutting element. The cutting element may extend through a window **24** in a shaft **26** of the catheter. As can be appreciated, the working element can be any other element such as an RF element, a visualization element or an implant delivery element. Typically catheter **20** may have a working diameter of 3 Fr to 7 Fr and have a working length of 60 cm to 180 cm.

The orientation of the working element **22** may be manipulated by rotating the shaft **26** so that a handle **28** can remain stationary while the shaft is rotated. The shaft may be rotatable in increments or may be adjustable to any angular orientation. In some embodiments the shaft is coupled to the handle in a manner which permits rotation of the shaft relative to the handle upon application of a modest torque to the shall. In other embodiments the shaft is rotationally fixed to the handle in a manner which does not permit rotation of the shaft relative to the handle upon application of a modest torque to the shaft.

Shaft manipulator **10** is rotatably and slidably coupled to shaft **26** and configured for one-handed use. Manipulator **10** is comprised of body **12** having lumen **11**, buttons **14**, springs **16** and pivot pins **18**. Buttons **14** are further comprised of arms **14***c* having holes therein for pivot pins to slidably fit through. Body **12** and buttons **14** may be made from polycarbonate, nylon, or other materials and may be injection molded or otherwise fabricated into the desired configuration. Body **12** may be molded in two halves and the halves bonded together by ultrasound, snap fit, adhesives, or other means following assembly of buttons, pivot pins and springs into body. In one embodiment two halves of body **12** are delineated by line A-A in FIG. **1**B. Faces **14***a*, **14***b* of button **14** may be textured for increased friction against shaft **26** or the fingers of an operator or both. Springs **16** and pivot pins **18** may be comprised of metal such as steel, spring steel, or other metals, or engineering polymer such as polyester, liquid crystal polymer, nylon, or other polymers.

Manipulator **10** is normally in an unlocked (FIG. **1**C) position with springs **16** extended so as to force faces **14***a* of buttons **14** away from shaft **26**. The manipulator is normally unlocked to permit the user to easily move manipulator **10** to any desired position along the shaft. For example, the user may move the manipulator with one hand to an exposed, distal portion of the shaft such as a portion of the shaft near an incision or near an introducer sheath while the other hand holds the handle **28**. Once the manipulator is positioned at the desired location along the shaft, rotation or translation (or both) of shaft **26** may be accomplished by pressing faces **14***b* of buttons **14** towards each other (FIG. **1**D) with one hand of the user followed by rotation or translation (or both) of manipulator **10** with the same hand.

Use of the catheter and manipulator of FIGS. **1**A to **1**D is now described. Catheter **20** is introduced into the patient in any known manner. When the user desires to manipulate the catheter, the user grasps manipulator **10** and moves it to an appropriate location for manipulating the catheter. The user then locks the manipulator onto the shaft by pressing on faces **14***b* so as to overcome force of springs **16** and move faces **14***a* into frictional contact with shaft **26**. The manipulator is then rotated, translated, or both to effect rotation, translation, or both of cutter **22** into contact with tissue such as atheroma. In some embodiments cutter **22** is extended outside of window **24** in a radial direction and catheter **20** is advanced through the vessel with cutter **22** extended to cut atheroma. In some embodiments atheroma is directed into interior of catheter by cutter **22**.

The shaft manipulator has been described as being in a normally unlocked position, however, in other embodiments the shaft manipulator may be in a normally locked position so that the user exerts pressure on the jaws to open the jaws rather than close the jaws. FIGS. **2**A to **2**D illustrate shaft manipulator **30** which is configured to be in a normally locked position. Manipulator **30** is rotatably and slidably coupled to shaft **26** and configured for one-handed use. Manipulator **30** is comprised of body **32** having lumen **31**, arms **34**, springs **36** and pivot pins **38**. Arms **34** have holes therein for pivot pins to slidably fit through, have faces **34***a* and have ends **34***b* which may be enlarged. Body **32**, arms **34**, faces **34***a*, springs **36** and pivot pins **38** may be made from materials, fabricated, and assembled substantially as described above for body **12**, buttons **14**, faces **14***a*, springs **16** and pivot pins **38** respectively.

Manipulator **30** is normally in a locked (FIG. **2**C) position with springs **36** extended so as to force faces **34***a* of arms **34** into frictional contact with shaft **26**. The manipulator is normally locked to permit the user to easily rotate or translate (or both) shaft **26**. The user may move manipulator **30** with one hand to any desired position along shaft **26** by pressing arms **34***b* towards each other so as to force faces **34***a* out of contact with shaft **26** (FIG. **2**D) followed by rotation or translation (or both) of manipulator **30** on shaft **26**. For example, the user may move the manipulator to an exposed, distal portion of the shaft such as a portion of the shaft near an incision or near an introducer sheath. An advantage of using the manipulator is that it may be easily positioned along the shaft and manipulated with one hand while the other hand holds the handle **28**.

Use of the catheter and manipulator of FIGS. **2**A to **2**D is now described. Catheter **20** is introduced into the patient in any known manner. When the user desires to manipulate the catheter, the user grasps manipulator **30** and unlocks the manipulator from the shaft by pressing on ends **34***b* so as to move faces **34***a* away from frictional contact with shaft **26**. The user then moves manipulator **30** to an appropriate location for manipulating the catheter. Pressure on ends **34***b* is then removed so as to allow springs **36** to move faces **34***a* into frictional contact with shaft **26**. The manipulator is then rotated, translated, or both to effect rotation, translation, or both of cutter **22** into contact with tissue such as atheroma. In some embodiments cutter **22** is extended outside of window **24** in a radial direction and catheter **20** is advanced through the vessel with cutter **22** extended to cut atheroma. In some embodiments atheroma is directed into interior of catheter by cutter **22**.

Referring to the embodiment of FIGS. **3**A and **3**B, another catheter **40** is shown for use with a manipulator **45**. Catheter **40** may be similar to catheter **20** described above but may be any other catheter with a working element, having shaft **46** similar to shaft **26** described above or another shaft, in any case with the addition of loop **42**. Manipulator **45** may be comprised of manipulator **10**, **30** described above or may be another manipulator. Handle **48** may be similar to handle **28** described above but may be any other handle.

Catheter **40** includes shaft **46** having a loop **42** positioned between the manipulator and the handle. Loop **42** may be formed of a flexible catheter portion which is designed to form the loop when the shaft is manipulated or may be a pre-shaped loop catheter portion, and when formed is comprised of gap **44**. Shaft **46** is fixedly coupled to handle **48** so that the shaft does not rotate or translate relative to handle. When manipulator **45** is rotated or translated, loop **42** is flexible enough to permit the distal portion of the shaft to be rotated or translated by the manipulator without requiring a change in the orientation or position of the handle. During rotation or translation of shaft **46** relative to handle **48** loop **42** may become larger or smaller in diameter **47** and gap **44** may increase or decrease, or both, to accommodate rotation or translation of shall **46** while allowing handle **48** to remain in an unchanged position.

Use of the catheter of FIGS. **3**A and **3**B is now described. The catheter is introduced into the patient in any known manner. When the user desires to manipulate the catheter, the user grasps the manipulator and moves it to an appropriate location for manipulating the catheter. The user then locks the manipulator onto the shaft. As the shaft is manipulated, the loop will constrict, expand, or change gap as necessary to accommodate rotation, translation, or both of the shaft while the handle position remains unchanged. In some embodiments cutter **22** is extended outside of window **24** in a radial direction and catheter **20** is advanced through the vessel with cutter **22** extended to cut atheroma. In some embodiments atheroma is directed into interior of catheter by cutter **22**.

FIGS. **4**A and **4**B illustrate another catheter **50** for use with a manipulator **55**. A distal portion of the shaft is shaped to provide an apposition force to urge the cutting element against the vessel wall. Catheter **50** may be similar to catheter **20** described above but may be any other catheter with a working element, having shaft **56** similar to shaft **26** described above or another shaft, in any case with the addition of jog **51***j* and preformed bends **51***p*, **51***d*. Catheter **50** is also comprised of working element **52** and window **54** which may be similar in construction, materials, and function as working element **22** and window **24** respectively. The window **54** is positioned at a radially inner position on the shaft so that the working element **52** is urged against the vessel wall when the catheter is positioned within a vessel. Jog **51***j* and preformed bends **51***p*, **51***d* cooperate to urge working element **52** into contact with material to be cut in a vessel. Manipulator **55** may be comprised of manipulator **10**, **30** described above or may be another manipulator. Use of manipulator **55** with catheter **50** is optional. Handle **58** may be similar to handle **28** described above but may be any other handle.

Catheter shaft **56** includes jog **51***j* and preformed bends **51***p*, **51***d*. Jog **51***j* is comprised of a hinge structure that allows distal portion **56***d* of shaft **56** to abruptly bend in relation to mid portion **56***m* of shaft **56**. Catheter structures capable of jog are further described in U.S. patent application Ser. No. 10/896,741, filed Jul. 21, 2004 and published as US 2005/0177068 A1, paragraphs [0092] to [0094], [0100] to [0102], to [0107] and FIGS. **1**, **1**A, **2**, **4**A and **4**B. The entire contents of US Patent Publication US 2005/0177068 are hereby incorporated herein in their entirety. In one embodiment the preformed bends are formed such that the mid portion and the portion of the catheter shall proximal of the mid portion lie within a first plane and the hinge element is configured to permit bending of the distal portion with respect to the mid portion only in the first plane. Preformed bends **51***p*, **51***d* may be formed by constraining distal portion **56***d* in metal molds followed by application of heat to cause catheter **56** to take the shape of the mold, or other means as are known to those of skill in the art. Preformed bend **51***p* has a lesser angle **53***p* than preformed bend **51***d* angle **53***d*. Preformed bend **51***p* angles of 90 to 150 degrees are contemplated. In one embodiment preformed bend **51***p* angles are 100 to 120 degrees. In other embodiments angle **53***p* are 95, 105, 110, 115, 125, 130 or 140 degrees. Preformed bend **51***d* angles **53***d* of 100 to 180 degrees are contemplated. In one embodiment preformed bend **51***d* angles are 120 to 140 degrees. In other embodiments angle **53***d* is 110, 130, 150, 160, or 170 degrees. The length from preformed bend **51***p* to preformed bend **51***d* is generally greater than the length from preformed bend **51***d* to jog **51***j*. Lengths from preformed bend **51***p* to preformed bend **51***d* of 0.5 to 2.0 inches are contemplated. In one embodiment length from preformed bend **51***p* to preformed bend **51***d* is 1.00 to 1.25 inches. In other embodiments lengths from preformed bend **51***p* to preformed bend **51***d* are 0.75, 1.5 or 1.75 inches. Lengths from preformed bend **51***d* to jog **51***j* of 0.125 to 1.0 inches are contemplated. In one embodiment length from preformed bend **51***d* to jog **51***e* is 0.375 to 0.625 inches. In some embodiments lengths from preformed bend **51***d* to jog **51***j* are 0.25, 0.5, 0.75 or 0.875 inches. The combined bends **51***d*, **51***p* and lengths between bends and between bend and jog cause catheter **56** to have a maximum excursion **56***e* from the unbent portion of catheter **56** to jog **56***j*. Generally, catheters of the invention are chosen to have an excursion greater than the diameter of the vessel or conduit that catheter **50** will be used within. Excursions **56***e* of 3 to 40 millimeters are contemplated. In one embodiment excursion **56***e* is 5 to 8 mm. In some embodiments excursions **56***e* are 4, 5, 6, 7, 8, 10, 12, 15, 20, 25, 30 or 35 millimeters.

When catheter **50** is positioned inside a vessel V of diameter D less than unconstrained excursion **56***e*, preformed bends **51***p* and **51***d* are forced to assume angles larger than their undeflected preformed angles while jog **51***j* allows distalmost portion of catheter **50** to become oriented along inner wall of vessel V. This cooperation between jog **56***j* and bends **51***p*, **51***d* forces or urges window **54** into contact with inner wall of vessel V as preformed bends attempt to restore their undeflected preformed angles. Preformed bend **51***d* maintains apposition force of cutter **52** and window **54** against the inner wall of vessel V at the low end of vessel diameters. As vessel diameter increases preformed bend **51***p* eventually starts to apply apposition force to the catheter tip as well. Urge forces of 0.05 to 0.5 lbs are contemplated. In one embodiment the urge force is 0.1 lbs. In some embodiments the urge force is 0.075, 0.2, 0.3 or 0.4 lbs. Working element **52**, such as a cutter, can be extended through window **54** to contact material to be cut, such as atheroma. During cutting, cutting forces tending to deflect cutter away from inside surface of vessel will be resisted by the urge forces produced as described above. The distal portion of shaft **56** can be rotated, translated, or both by manipulator **55** (if used) to assure that window **54** is circumferentially oriented so as to contact the material to be cut.

Use of the catheter of FIGS. **4**A and **4**B is now described. A catheter **50** having excursion **56***e* greater than the inside diameter of vessel V is chosen. Optionally, the catheter is introduced over a guidewire into the patient in any known manner to a location in vessel V where material is to be removed. The catheter, when introduced over a guidewire, tends to straighten somewhat and follow the guidewire to the location. Preformed bends **51***p*, **51***d* in cooperation with jog **51***j* urge window **54** against inner wall of vessel V. In some embodiments cutter **52** is extended outside of window **54** in a radial direction and catheter **50** is advanced through the vessel with cutter **52** extended to cut atheroma. In some embodiments atheroma is directed into interior of catheter by cutter **52**. Optionally, when the user desires to manipulate the catheter, the user grasps manipulator **55** and moves it to an appropriate location for manipulating the catheter. The user then locks the manipulator onto shaft **56** and rotates, translates, or both the shaft while handle **58** position remains unchanged.

FIGS. **5**A to **5**C illustrate another catheter **60** for use with a manipulator **65**. A distal portion of the shaft is shaped to provide an apposition force to urge the cutting element against the vessel wall. Catheter **60** may be similar to catheter **20** described above but may be any other catheter with a working element, having shaft **66** similar to shaft **26** described above or another shaft, in any case with the addition of jog **61***j* and continuously decreasing radius curve **61**. Jog **61***j* may be similar in construction, materials, and function to jog **51***j*. Catheter **60** is also comprised of working element **62** and window **64** which may be similar in construction, materials, and function as working element **22** and window **24** respectively. Working element **62** is positioned at a radially inward position on the shaft so that the working element **62** is urged against the vessel wall when the catheter is positioned within a vessel. Jog **61***j* and continuously decreasing radius curve **61** cooperate to urge working element **62** into contact with material to be cut in a vessel. Manipulator **65** may be comprised of manipulator **10**, **30** described above or may be another manipulator. Use of manipulator **65** with catheter **60** is optional. Handle **68** may be similar to handle **28** described above but may be any other handle.

Catheter shaft **66** includes jog **61***j* and continuously decreasing radius curve **61**. Continuously decreasing radius curve **61** may be formed by constraining distal portion **66***d* of catheter shaft **66** in metal molds followed by applying heat to cause distal portion **66***d* to take the shape of the mold, or other means as are known to those of skill in the art. Distal portion **66***d* may curl around at least 90 degrees up to at least 720 degrees. FIG. **5**A shows the shaft curling about 360 degrees and FIG. **5**B shows the shaft curling about 720 degrees. In other embodiments distal portion **66***d* curls around 120, 150, 180, 240, 300, 480, or 600 degrees. The maximum curve diameter **63** may vary from 3 mm to 50 mm although the maximum curve diameter may be outside this range depending upon the particular application. In one embodiment the maximum curve diameter is 10 to 12 mm. In other embodiments the maximum curve diameter is 4, 6, 8, 15, 20, 25, 30, or 40 mm.

In another embodiment, the continuously decreasing radius curve **61** may be comprised of a number of discrete preformed bends (not shown). As can be appreciated, the number of sections of decreasing radius may vary. For example, catheters having from 2 to 100 sections are contemplated. In other embodiments, the catheter may have 4, 6, 8, 10, 15, 20, 40, 60, 75, or 100 sections. In yet another embodiment, catheter has an infinite number of sections as disclosed by the continuously variable embodiment of FIGS. **5**A to **5**C.

The continuously decreasing radius is intended to provide a relatively uniform apposition force over a range of vessel diameters. Of course, the actual apposition force may vary considerably during use since vessel geometry and size vary considerably from patient to patient; however, the shape of the shaft tends to provide a uniform force over a range of vessel sizes.

When catheter **60** is positioned inside a vessel V of diameter D less than maximum curve diameter **63**, the continuously decreasing radius curve **61** is forced to increase in diameter while jog **61***j* allows distalmost portion of catheter **60** to become oriented along inner wall of vessel V. This cooperation between jog **56***j* and curve **61** forces or urges window **64** into contact with inner wall of vessel V as curve **61** attempts to restore its undeformed diameter. Working element **62**, such as a cutter, can be extended through window **64** to contact material to be cut, such as atheroma. During cutting, cutting forces tending to deflect cutter away from inside surface of vessel will be resisted by the urge forces produced as described above. The distal portion of shaft **66** can be rotated, translated, or both by manipulator **65** (if used) to assure that window **64** is circumferentially oriented so as to contact material to be cut.

Use of the catheter of FIGS. **5**A to **5**C is now described. The catheter is introduced over a guidewire into the patient in any known manner to a location where material is to be removed. The catheter, when introduced over a guidewire, tends to straighten somewhat and follow the guidewire to the location. Curve **61** in cooperation with jog **61***j* urge window **64** against inner wall of vessel V. In some embodiments cutter **62** is extended outside of window **64** in a radial direction and catheter **60** is advanced through the vessel with cutter **62** extended to cut atheroma. In some embodiments atheroma is directed into interior of catheter by cutter **62**. Optionally, when the user desires to manipulate the catheter, the user grasps manipulator **65** and moves it to an appropriate location for manipulating the catheter. The User then locks the manipulator onto the shaft **66** and rotates, translates, or both the shaft while handle **68** position remains unchanged.

The present invention has been described in connection with preferred embodiments but may, of course, be practiced while departing from the above described illustrative embodiments.

What is claimed is:

1. A method of performing a procedure at a treatment site in the lumen of a blood vessel comprising:

providing an elongate tubular shaft having distal and proximal ends and a sidewall defining a lumen, the elongate tubular shaft having a proximal bend, a distal bend and a hinge element, the proximal bend defining a first undeflected angle prior to insertion of the elongate tubular shaft into the lumen of the blood vessel, the distal bend defining a second undeflected angle prior to insertion of the elongate tubular shaft into the lumen of the blood vessel that is greater than the first undeflected angle, the proximal and distal bends being oriented in a first direction, the hinge element being spaced proximally of the distal end of the elongate tubular shaft and distally of the distal bend, the distal bend being positioned between the proximal bend and the hinge element, a distal portion of the elongate tubular shaft extending between the hinge element and the distal end of the elongate tubular shaft and a mid portion of the elongate tubular shaft extending between the hinge element and the proximal bend, the distal portion including a window extending through the sidewall between the hinge element and the distal end of the elongate tubular shaft;

advancing the elongate tubular shaft through the lumen of the vessel to the treatment site, wherein the proximal bend has a first deflected angle greater than the first undeflected angle and the distal bend has a second deflected angle greater than the second undeflected angle when the elongate tubular shaft is at the treatment site;

orienting the elongate tubular shaft in a position where the proximal and distal bends cause the distal portion of the elongate tubular shaft to bend with respect to the mid portion of the elongate tubular shaft at the hinge element in a second direction opposite the first direction to urge the window against a wall of the vessel in a desired location at the treatment site; and

performing a procedure through the window at the treatment site with a working element disposed within the lumen of the elongate tubular shaft while the window is urged against the wall of the vessel.

2. The method of claim **1** wherein the hinge element is configured to permit bending of the distal portion with respect to the mid portion only in the first and second directions.

3. The method of claim **1** wherein the first and second undeflected angles are selected to urge the window against the wall of the vessel at a force in the range of about 0.05 to 0.5 pounds.

4. The method of claim **1** wherein the first undeflected angle is in the range of about 90° to 150° and the second undeflected angle is in the range of about 100° to 180°.

5. The method of claim **1** wherein a length from the proximal bend to the distal bend is greater that a length from the distal bend to the hinged element.

6. The method of claim **1** wherein a length between the proximal and distal bends is in the range of about 0.5 to 2.0 inches.

7. The method of claim **1** wherein a length between the distal bend and the hinge element is in the range of about 0.375 to 0.625 inches.

8. The method of claim **1** wherein the first and second undeflected angles are selected to form a maximum excursion of the elongate tubular shaft between the proximal bend and the hinge element greater than a diameter of the vessel at the treatment site.

9. The method of claim **1** wherein the working element is an atherectomy cutting device and the procedure comprises removing material from the wall of vessel.

10. The method of claim **1** wherein the distal portion is curved with a continuously decreasing radius of curvature.

11. The method of claim **10** wherein the curved distal portion forms a continuous curve in the range of about 90 degrees to 180 degrees.

12. The method of claim **10** wherein a maximum curve diameter of the curved distal portion is in the range of about 3 mm to about 50 mm.

13. A method of performing a treatment at a site in a body lumen, the method comprising:

inserting an elongate tubular shaft into the lumen, the elongate tubular shaft having distal and proximal ends and a sidewall defining a lumen, the elongate tubular shaft having a first bend, a second bend spaced a predetermined distance distally of the first bend and a window extending through the sidewall, the window being positioned distally of the second bend and proximally of the distal end of the elongate tubular member, the first bend defining a first preformed angle, the second bend defining a second preformed angle greater than the first preformed angle,

moving the elongate tubular shaft to deflect the first bend to define a first deflected angle greater than the first preformed angle and to deflect the second bend to define a second deflected angle greater than the second preformed angle, whereby the first and second preformed angles and the predetermined distance urge the window against a site in the body lumen.

14. The method of claim **13** wherein inserting the elongate tubular shaft into the lumen comprises inserting the elongate tubular shaft into a blood vessel.

15. The method of claim **13** and further comprising performing a procedure through the window at the site in the body lumen.

16. A method of performing a procedure at a treatment site in the lumen of a blood vessel comprising:

inserting into the lumen of a blood vessel an elongate tubular shaft having distal and proximal ends and a sidewall defining a lumen, the elongate tubular shaft having a proximal bend, a distal bend and a hinge element, the elongate tubular shaft being configured such that when unconstrained the proximal bend defines a first angle and the distal bend defines a second angle greater than the first angle, the elongate tubular shaft being further configured such that when constrained within the lumen of the blood vessel the proximal bend is deflected to define a first deflected angle greater than the first angle and the distal bend is deflected to define a second deflected angle greater than the second angle, the hinge element being spaced proximally of the distal end of the elongate tubular shaft and distally of the distal bend, the distal bend being positioned between the proximal bend and the hinge element, a distal portion of the elongate tubular shaft extending between the hinge element and the distal end of the elongate tubular shaft, the distal portion including a window extending through the sidewall between the hinge element and the distal end of the elongate tubular shaft;

moving the elongate tubular shaft at the treatment site so that the proximal bend, distal bend, and hinge element urge the window against the wall of the vessel at the treatment site; and

performing a procedure through the window at the treatment site with a working element disposed within the lumen of the elongate tubular shaft while the window is urged against the wall of the vessel.

17. The method of claim **16** wherein performing the procedure through the window at the treatment site comprises using an atherectomy cutting device.

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